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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:

PETER T. O'HEERON

Application No.: 10/646,675

Filed: 08/22/2003

For: Medical Procedure Kit

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Group Art Unit: 3728

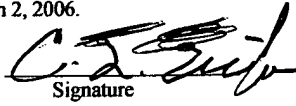
Examiner: David Fidei

MAIL STOP APPEAL BRIEF -
PATENTS

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<u>Clarence E. Eriksen</u> Typed or printed name	<u>27,734</u> Registration Number

Sir:

REPLY BRIEF

Pursuant to 37 C.F.R. § 41.41, Assignee NeoSurg Technologies, Inc., files its Reply Brief in triplicate.

I. INTRODUCTION

The Examiner continues to assert in his Answer, as he did in the final office action, that the prior art somehow discloses an obturator comprising "an orientation indicator located near the proximal end [of the obturator] which enables a user to determine by touch the relative position of the tip at the distal end [of the obturator]," as required by claim 18. In order to make his rejections, the Examiner has asserted that the references of record disclose subject matter that is not even suggested by the references. When the references are construed properly, no substantial evidence exists to support the

Examiner's § 102 rejection of claim 18 based on the Vidal patent, or the Examiner's § 103 rejection of claim 18 based on the Vidal patent, or the §103 rejection of claim 18 based on the combination of the Johnson and Metcalf patents. Accordingly, these rejections must be reversed.

II. The "Clearly Erroneous" Standard is Inapplicable

Significantly, the Examiner begins his arguments by invoking the "clearly erroneous" standard of Fed. R. Civ. P. 52 and invites this Board to compare *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931 (Fed. Cir. 1987) (*en banc*) to some unidentified case. (Answer, p. 8). While the Examiner does not state what such a comparison would show, the Examiner is apparently of the view that the clearly erroneous standard of Rule 52 applies to the rejections made by him in the final office action. The Examiner is simply wrong. *Dickinson v. Zurko*, 527 U.S. 150, 50 USPQ2d 1930 (1999).¹

III. No Substantial Evidence Exists to Support the § 102 Rejection of Claim 18 Based on the Vidal Patent

The portion of Vidal upon which the Examiner relied to make the §102 rejection of claim 18 is Figure 16, which illustrates an obturator having a proximal portion 201 and a handle 202 adapted to be manually grasped. *See also*, col. 11, ln. 26-32. As shown in Figure 16, the diameter of the handle 202 is greater than the diameter of the shaft of the proximal portion 201.

¹ While the Examiner's reliance on Rule 52 is misplaced, the Examiner's rejections of claim 18 are reversible not only under the substantial evidence standard, but also under the clearly erroneous standard.

In attempting to justify his rejection based on Vidal, the Examiner makes the statement in his Answer that the obturator in Vidal “is far from uniform in construction with an equal diameter from one to the other.” (Answer, p. 8). It is unclear what is meant by this statement, since the shaft of proximal end 201 has a uniform diameter along its length. The Examiner then asserts that where the shaft 201 in Vidal meets handle 202, there is a “sharp distinction” in shape where a “raised surface” is defined over the rest of the device “that manifestly is capable of functioning as an orientation indicator.” *Id.* Notably, the Vidal patent does not utilize the terms “sharp distinction” or “raised surface.”

The Examiner apparently regards the “sharp distinction” in shape as the difference between the diameter of the shaft of proximal portion 201 and the diameter of handle 202. However, nowhere does the Vidal patent characterize the difference in diameters between the shaft of proximal portion 201 and handle 202 as any sort of indicator of the orientation of the tip at the distal end. Indeed, the word “orientation” (or a word of similar import) is not to be found in the Vidal patent.

Moreover, as demonstrated in Appellants’ opening brief, the difference in diameters between the shaft of proximal end 201 and handle 202 in the obturator disclosed in the Vidal patent cannot and indeed does not provide any information to the user about the orientation of the tip at the distal end of obturator. This is because the difference in diameters between the shaft of proximal end 201 and handle 202 is substantially the same for all points around the circumferences of shaft 201 and handle 202. Thus, the only “information” that can be obtained by touch from this difference in diameters is that a change in diameter exists near the most proximal part of the obturator.

That is no information at all concerning the orientation of the tip at the distal end of the obturator.

In contrast, a user of the present invention knows by touching orientation indicator 20 (FIG. 3) that the tip of the obturator is oriented as shown in FIG. 3 and that the tip is not rotated 90° from the position shown in FIG. 3.

Another reason that Claim 18 is not anticipated by Vidal is because claim 18 requires that the proximal and distal ends and the shaft be formed as a "monolithic" structure.² The Examiner ignored the limitation monolithic in claim 18 by determining that the term was of "no patentable moment." (Final Office Action, p. 4). That action was arbitrary on the part of the Examiner and not in accordance with the law, because the law requires that a prior art reference describe all of the elements in a claim, arranged as in the claim, for the reference to be an anticipation. *C.R. Bard, Inc. v. M3 Systems Inc.*, 157 F.3d 1340, 1349 (Fed. Cir. 1998). The law thus requires strict identity between the claim at issue and the prior art reference for anticipation to exist. *Trintec Industries, Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296 (Fed. Cir. 2002) (reference disclosing a color printer did not anticipate a claim requiring a color photocopier).

The Examiner lamely attempts in his Answer to justify his position that the term "monolithic" is somehow a product by process limitation. (Answer, p. 9). The Examiner does not cite any authority to support his position and it is believed that no such authority

² The limitation "monolithic" was used in claim 18 in view of the Examiner's position in the first Office Action (January 11, 2005) that the term "integral" (as used in claims 2-9 as filed) was not limited to a unitary structure. Appellant had used the term "integral" to mean a unitary structure, and the term "monolithic" is also used in its ordinary manner to mean that the proximal and distal ends and the shaft are formed as a single unit, i.e. they are a unitary structure. See, *Merriam-Webster's Collegiate Dictionary*, p. 753 (10th Ed. 1996).

exists. It is respectfully submitted that the Examiner's position that monolithic is a product by process limitation is not well-founded, and should be rejected.

In summary, the Vidal patent does not disclose an orientation indicator or a monolithic structure as called for by claim 18 of this application. Since strict identity does not exist between claim 18 and the Vidal patent, the § 102 rejection of claim 18 based on the Vidal patent must be reversed.

IV. The § 103 Rejection of Claim 18 Based on Johnson in View of Metcalfe Must Be Reversed

The Johnson patent is directed to an obturator for use in a root canal procedure. Significantly, the Examiner concedes in his answer that any use of the device of the Johnson patent as an obturator for endoscopic surgery would require substantial reconstruction and redesign. (Answer, p. 12). The Examiner also did not challenge Appellant's assertion in its opening brief that the manner in which Johnson's device is constructed and the way it is used evidence that it is neither designed nor suitable for use in endoscopic surgery. These facts clearly evidence that the § 103 rejection of claim 18 based on Johnson and Metcalf is erroneous. *In re Ratti*, 270 F.2d 810, 813 (CCPA 1959).

Undaunted, the Examiner argues that "[a] statement of intended use, which is merely recited in the preamble does not limit the recitations of structure, which follow the preamble to the indicated use." (Answer, p. 12). An extensive body of precedent exists, however, on the issue of whether a statement in a claim of purpose of intended use constitutes a limitation for purposes for patentability. *In re Stencel*, 4 USPQ 2d 1071, 1073 (Fed Cir. 1987); *In re Duva*, 156 USPQ 90, 94 (CCPA 1967) (the difference in

intended use between the prior art reference and the applicant's invention can be considered in determining whether applicant's claims would have been obvious). In this case, the statement of intended use should be considered a limitation because claim 18, besides specifying that the obturator is for use in endoscopic surgery, calls for two features which are relevant to endoscopic surgery and which are not shown, described or suggested in Johnson's root canal device.

First, the Johnson patent does not describe an orientation indicator which, as previously discussed, enables the user to determine by touch the relative position of the tip at the distal end of the obturator. Second, claim 18 calls for the obturator to have a distal end with a tip that is used either to cut or separate tissue, and the device disclosed in the Johnson patent has no such tip.

Turning to the latter difference first, the Appellant asserted in its opening brief that it appeared to be impossible to use the tip of Johnson to cut or separate tissue. The Examiner maintains in his Answer that the contrary is true and that "[a]s shown in figure 5, the tip [of Johnson] is used to separate tissue, compare the left and right apexes 30 of figure 5." (Answer, p. 11). This position is absolutely without merit.

Johnson uses the reference designator 28 to designate the root canal. (See, FIG. 5 and Col. 4, ln. 6-9). The Johnson patent clearly describes that a root canal is typically prepared by the dental practitioner using elongated cylindrical files in the removal of pulpal material. (Col. 2, ln. 13-30). Thus, the root canal 28 shown in FIG. 5 of Johnson is the canal after preparation by using such cylindrical files. In other words, the tip of the obturator in Johnson, when inserted in the root canal is not used to separate any tissue.

Rather, that obturator is just fitting into the canal in the tooth that was made using the cylindrical files.

Further, Johnson does not disclose an orientation indicator. The Examiner's assertion that washer 22 and shaft 18 in Figures 1 and 2 of Johnson constitute an orientation indicator is meritless. The difference between the diameter of washer 22 and the diameter of shaft 18 is the same at all circumferential points where washer 22 and shaft 18 meet. That difference in diameter does not provide the user any information about the orientation of the tip at the distal end of the obturator, just as the difference in diameters of the shaft of proximal end 201 and handle 202 Vidal did not provide any information to the user about the orientation of the tip at the distal end.

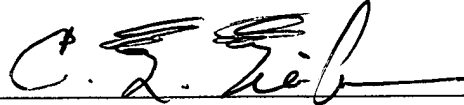
The § 103 rejection based on the combination of Johnson and Metcalf is thus fundamentally flawed and cannot stand.

V. CONCLUSION

The Examiner's rejection of claims 8-9 and 18 should be reversed and such action is requested.

Date: March 2, 2006

Respectfully submitted,

A handwritten signature in black ink, appearing to read "C. E. Eriksen", written over a horizontal line.

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